IN THE UNITED STATES PATENT & TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

SERIAL NO. 09/691,671

FILED: OCTOBER 18, 2000 GROUP ART UNIT: 3763

INVENTOR: MICHAEL J. WILCOX EXAMINER: KATHRYN THOMPSON

FOR: OPTHALMIC IMPLANT

APPELLANTS' APPEAL BRIEF

Honorable Commissioner of Patents and Trademarks

Washington, D.C. 20231

Sir:

REAL PARTY IN INTEREST

The real party in interest in this appeal is MICHAEL J. WILCOX.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences that will directly affect or be directly effected by, or have a bearing on, the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1-42, 46, and 51 have been cancelled. Claims 43, 44, and 47 were rejected and are appealed. Claims 45, and 48-50 were withdrawn from consideration and are appealed.

STATUS OF AMENDMENTS

No amendments were filed subsequent to final action.

SUMMARY OF THE INVENTION

The present invention relates to a tubular shunt implant for the control of intraocular pressure in glaucomatous eyes. Glaucoma is a disease characterized by high fluid pressure within the eyeball that leads to damage of retinal nerve fibers and a resulting loss of vision.

The eyeball is bulb filled with a fluid called aqueous humor. Positive pressure of this fluid is necessary to maintain attachment of the retina to the lateral and posterior aspects of the inside of the bulb. The anterior portion of the eyeball contains the lens and an anterior chamber in front of the lens that is covered by a domed cornea. Bilaterally of the lens and just below the root of the annular iris that circles the lens are ciliary muscles and ciliary processes that continually produce the aqueous humor. Just above the root of the iris and at the angle of the anterior chamber is a spongy mass of tiny channels (trabecular meshwork) through which the aqueous humor exits the eye into the sclera. The sclera is a fibrous tunic that forms the outer envelope of the eye, and which contains the scleral venous sinus, also know as "Schlemm's canal." The canal is a significant part of the drainage system for conduction of the aqueous humor from the trabecular meshwork to the venous system of the eyeball.

An over abundance of aqueous humor within the eyeball increases the fluid pressure therein, causing the symptoms of glaucoma. This condition is caused by either an over production of aqueous humor by the ciliary processes or blockage of the drainage channels in the trabecular meshwork. Establishing accessory drainage through the trabecular meshwork to alleviate the high fluid pressure that damages the retina is the only effective treatment for glaucoma.

The purpose of the present invention is to provide a device for implantation in the eyeball that will conduct aqueous humor from the anterior chamber into the interstices of the trabecular meshwork, where the device has initiated the formation of one or more small diameter cylindrical filtration capsules (blebs) that constitute accessory drainage routes for the aqueous humor. In its most basic form, the implant device comprises a fluid conducting cylindrical tube of approximately four hundred micrometers in diameter having at least one laterally extending opening in the sidewall with a laterally extending projection formed with the removed portion of the sidewall. When disposed within the trabecular meshwork the laterally extending projection from the open sidewall of the tube forms a nest or point of origin (nidus) for the collection of cells that deposit fibrous tissue and create an expandable cellular capsule. When aqueous humor in the anterior chamber is inducted into the open end of the tube the aqueous flows into the nidus and expands the cellular capsule into a bleb outside the trabecular meshwork. Through osmosis the fluid passes through the bleb and into the orbital tissue outside the eyeball, thereby reducing intraocular pressure. The preferred form of the invention contemplates a conduit tube

having more than one laterally extending projection in order to form a plurality of nidi with their associated blebs to maximize the accessory filtration offered by the implant.

The conduit tube of the inventive implant device is also provided with one ligature proximal to the input end of the tube that closes the conduit tube to fluid flow past the ligature. Preventing any aqueous flow through the tube immediately following the implant precludes excess drainage that would reduce the ocular pressure to an undesirably low level because of loss of aqueous during the surgery. Within a week or so of the implant surgery, and after the need for ocular fluid pressure modification is determined, the input ligature is released to implement the function of the implant. In the embodiments of the invention that provide for multiple openings in the sidewall, with corresponding laterally projecting nidi-forming means, intermediate ligatures may be interspersed between each lateral projection. Releasing one of these ligatures opens the conduit tube for aqueous flow into the next in line nidi-forming projection of the tube, allowing the associated bleb to inflate and supplement the aqueous filtration provided by the first in line nidi-forming projection. This configuration allows the implant to be adjusted for precise accessory aqueous humor filtration by release of one or more of the intermediate ligatures as the need is determined.

To prevent the implanted tube from migrating into the anterior chamber, the distal end of the tube may be separated into two or more furcations that are disposed in the sclera adjacent the trabecular meshwork.

ISSUES

The issues presented on appeal are:

(1) Whether claims 43 and 47 are anticipated under 35 U.S.C. 102(b) by Kousai, US 4,883,468.

(2) Whether claim 44 is obvious and unpatentable over Kousai, US 4,883,468 in view of Odrich, US 6,471,666.

(3) Whether claim 43 is generic to the elected species and to the species defined by withdrawn claims 45 and 48-50 and therefor, whether those non-elected species claims are patentable.

GROUPING OF CLAIMS

Claims 43 and 47, have been rejected as being anticipated under 35 U.S.C. § 102(b) by Kousai, US 4,883,468. The claims of this group do not stand or fall together, as explained within the Argument portion of this brief.

Claim 44 has been rejected under 35 U.S.C. § 103(a), as being unpatentable over Kousai, US 4,883,468, in view of Odrich, US 6,471,666.

ARGUMENT

1. **Appellant's claims 43 and 47 are not anticipated under 35 U.S.C. 102(b) by Kousai, US 4,883,468 because the reference does not disclose all of the elements of the claimed combination or their equivalent.**

Claims 43 and 47 stand rejected under 35 U.S.C. §102(b) as being anticipated by Kousai ('468). In explaining the rejection, the examiner states:

> "Kousai discloses a tube comprising an elongated fluid conducting conduit 31 (*the cannula could conduct fluid, but that is not its purpose*), a sidewall and an interior passage (*agreed*), at least one longitudinally extending opening in the sidewall that exposes the interior passageway (Figure 14) (*this is true only after the strip 34 is peeled back for the purpose of removing the introduction cannula 11 from the catheter*), at least one nidi-forming means 33 (***disagree***) and an anchoring means 35 (***disagree***)"
> Final Rejection, pages 2 and 3.

The Kousai Patent, No. 4,883,468

The Kousai patent disclosure relates to a synthetic resin introduction cannula used for introducing and indwelling a rod-like medical tool such as a catheter, a guide wire, or the like in a blood vessel. (col. 1, ll. 8-10)

Kousai's device is responsive to his recognition of the difficulty of removing an introduction cannula following its use as a guide for placing a catheter. Related prior art attempts to solve the problem through the use of splitting mechanisms have resulted in reducing the structural integrity of the cannula without corresponding improvement in the ease of removal. Kousai's solution to the problem is an introduction cannula that is manufactured as a single unit to avoid premature splitting. Kousai accomplishes this objective by proposing two embodiments of a cannula (11 and 31) with the main tubular body being composed of polypropylene or similar material, and a strip member (13 and 34) for creating a split longitudinally of the body that is composed of a denser thermoplastic material, the parts of which are manufactured as a single unit. The

process for manufacturing the device is the significant aspect of the Kousai disclosure.

To remove the cannula from the inserted catheter (or other inserted rod-like device) the strip member (34 in Fig. 13 & 14) is pulled upward to split the body of the introduction cannula away from the catheter. Col 7, ll. 51-57.

Appellant's Invention *vis-à-vis* Kousai

Appellant's invention relates to the regulation of intraocular pressure in glaucomatous eyes. Appellant provides an accessory means for forming and controlling blebs in the trabecular meshwork of the eye in order to conduct aqueous humor, while at the same time preventing excess scarring or obstruction of vision. Appellant's invention is conceptually and mechanically dissimilar to the apparatus of Kousai. The structure of Appellant's invention consists of a flexible tube with laterally extending nidi-forming means for implantation into the eye to create replacement or accessory conduction of aqueous humor from the anterior chamber of the eyeball to the venous system. The nidi-forming means are part of the fluid-conducting conduit. To the contrary, the strip 34 of Kousai will not work for its intended purpose unless it is completely removed from the tubular structure 33 in order to open the tube up for removal from the implanted catheter. The strip 33, cited by the examiner as being the structure that corresponds to Appellant's "nidi-forming means" corresponds more to Appellant's tube than it does to any part that is partially separated from the tube. Not only is the ophthalmicly oriented implant structure defined by Appellant's claims totally different than the introduction cannula of Kousai, Appellant's inventive objective

is entirely unrelated to the objective of Kousai and lies within an wholly disparate field of medical practice.

Claim 43

The invention, as defined in independent claim 43, comprises a fluid conducting conduit 32 having distal 36 and proximate 34 ends, a sidewall, an interior passageway 40 and at least one longitudinally extending opening in the sidewall that exposes the interior passageway and at least one nidi-forming structure 38 carried by the conduit and extending laterally therefrom. The nidi-forming means implements the formation of at least one aqueous filtration bleb in the trabecular meshwork of the eyeball.

The examiner's § 102(b) rejection of claim 43 is in error for two reasons: (1) the structures defined by claim 43 and those disclosed by Kousai are not the same, nor are they equivalent; and (2) the apparatus of Kousai and Appellant serve exceptionally distinct functions.

To justify the rejection the examiner has erroneously chosen to equate the terms of claim 43 with structures identified diagrammatically in the Kousai drawings. First, the examiner has erroneously chosen to equate the term "elongated fluid conducting conduit," in claim 43 to the flexible hollow tubular body 31 of Kousai. The tubular body, or introduction cannula, is not a "fluid conducting conduit." On the contrary, in the context of Kousai's disclosure, the cannula is a "guide" for the introduction of a "rod-like medical instrument."

Second, the examiner has erroneously chosen to equate the means-plus-function element, "nidi-forming means carried by the conduit and extending

laterally therefrom to implement the formation of at least one aqueous filtration bleb in the tissue of the eyeball" of claim 43 with the "first strip-member 33" of Kousai. *See* Col. 6, ll. 9-10 and Figures 12-14 of Kousai. While the "second strip member" 34 of Kousai arguably has a similar appearance to Appellant's nidi-forming means 38, the strip member 33 does not even bear any physical resemblance to the "nidi-forming means" that is described in Appellant's specification and illustrated in the drawings. The cited strip member 33 of Kousai is grossly unrelated in purpose, function, structure and material to the recited nidi-forming means of claim 43. Clearly, the limitations "elongated fluid conducting conduit" and "nidi-forming means" of claim 43 do not equate to the apparatus disclosed by Kousai and relied upon by the examiner as the basis for the §102 rejections.

Claim 47

Claim 47 is dependant from claim 43 and adds the additional limitation of "anchoring means." This additional limitation in claim 47 is the basis for earlier stating that claim 47 does not stand or fall with claim 43. The anchoring means corresponds to the furcated distal ends 32, 132 and 242 of the implanted tube that serve the function of anchoring the implant in the sclera to prevent the migration of the implant into the anterior chamber of the eyeball. Claim 47 is allowable for the same reasons as those given for claim 43.

In rejecting claim 47 the examiner chose to equate "anchoring means" with the inserted catheter (35) of Kousai, depicted in his Figures 13 and 14. The cited catheter is not even a part of the insertion cannula disclosed by Kousai. It

manifestly is not "appended to the conduit to prevent the conduit from migrating from its placement site." The catheter 35 of Kousai is merely an illustrated example of a "rod-like medical instrument" that can be guided into a blood vessel by Kousai's introduction cannula. It is not, in any conceivable usage, an "anchoring means," as that term is defined in Appellant's specification. The catheter 35 of Kousai is a device by which fluids can be administered intravenously to a patient. No "anchoring means" is described or disclosed in the Kousai patent. The examiner's equation of "anchoring means appended to the conduit to prevent the conduit from migrating from its placement site" with an exemplary catheter that is independent from the Kousai apparatus is clear error.

The Error of the Section 102 Rejections

In order to anticipate a means-plus-function claim, the reference "must disclose the recited function *identically*." *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364 (C.A. Fed. 2002). The "nidi-forming means" of claim 43 corresponds to Appellant's structural elements 32(a), 38, 132(a) and 138, serving the function of forming a focal point, nest, or nidus, for capsule formation on the scleral surface of the eyeball. The strip-member 33 of Kousai (or for that matter, strip 34) is not intended to serve, does not serve and could not serve the function of forming nidi in an eyeball. It does not serve as a means to form a capsule in an eyeball. It could not be implanted in an eyeball. The purpose of Kousai's strips 33 and 34 is to split the introduction cannula after it has served its function of guiding the catheter so that it may be removed from the catheter, a function not even remotely analogous to the function of the nidi-forming means of claim

43. Not only is Kousai an inappropriate § 102 reference because it fails to show or disclose each element of the claimed combination, no one skilled in the art seeking to develop an eye implant for the treatment of glaucoma would find any suggestion or motivation to do so in the Kousai disclosure.

In the context of a means-plus-function claim, the invalidating prior art must disclose not simply a means for achieving the desired function, but rather the *particular structure* recited in the written description corresponding to that function, or an equivalent thereof. *See In re Donaldson Co., Inc.*, 16 F.3d 1189, 1193, 29 USPQ2d 1845, 1849 (Fed.Cir.1994). In addition to its notoriously disparate function, neither of the strips 33 nor 34 of Kousai are similar to the structure of the nidi-forming means detailed in the Appellant's specification, shown in his drawings and recited in the rejected claims. Basically, there is not a single redeeming feature in the examiner's section 102 rejection of claim 43 or the arguments made on behalf of the rejection.

The limitations of claims 43 and 47 clearly distinguish the combinations defined thereby from the Kousai introduction cannula by both function and structure. The rejection of these claims is erroneous under any set of standards for a section 102 rejection. Anticipation can only be established when a single prior art reference discloses each and every element of a claimed invention or its equivalent. *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 772, 218 USPQ 781,789 (Fed. Cir. 1983). Kousai does not disclose an "elongated fluid conducting conduit," "nidi-forming means" or an "anchoring means" and, accordingly, rejection of claims 43 and 47 under § 102(b), must be reversed.

2. The apparatus defined by claim 44 is not obvious and unpatentable over Kousai, US 4,883,468 in view of Odrich, US 6,471,666.

Claim 44 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Kousai, U.S. No. 4,883,468, in view of Odrich, U.S. No. 6,471,666. The examiner explains that:

> "[I]t would have been obvious to one with ordinary skill in the art to use the teachings of Odrich to modify the invention of Kousai and add a ligature to Kousai in order to constrict the flow of aqueous in the tube."

However, it is inconceivable how it might be obvious to one skilled in the art to combine the ligature of Odrich with the introduction cannula of Kousai to bring into being the ophthalmic implant of Appellant, as defined in his claim 44. The rejection of claim 44 is clearly erroneous and must be reversed. Being dependent from claim 43, claim 44 is allowable for the same reasons as given above for claim 43.

3. Claim 43 is generic to the elected species and to the species defined by withdrawn claims 45 and 48-50 and therefor, those non-elected species claims are also patentable.

Claims 45, and 48-50 were withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected species for lack of a generic linking claim. The decision of the examiner to withdraw these claims is in error. Claims 45 and 48-50 are dependent from claim 43 and are substantively allowable for the same reasons as given above for claim 43. Claim 43 is generic to all four species, A (Figures 4,6,7,10 and 11), B (Figures 5,15 and 16), C

(Figures 8 and 9) and D (Figures 12,13 and 14). The "elongated fluid conducting conduit" and the "at least one nidi-forming means" of Claim 43 are found within all four species. Claim 45 reads on species B and C. Claims 48 and 49 read on species A, B, and C. Claim 50 reads on species B. The decision of the examiner to withdraw these claims from consideration for failure to provide a generic linking claim should be overturned in view of the above argument for allowability of generic claim 43.

CONCLUSION

As required for a section 102 rejection, Kousai does not disclose each and every element of claim 43. The tubular body 43 of Kousai's introduction cannula is not disclosed as a *elongated fluid conducting conduit* nor does it function as such. It is a is guide for a rod-like medical instrument. The examiner's equating of the first strip 33 (or even the second strip 34) of Kousai's splitable introduction cannula to the *nidi-forming means that facilitates the formation of a bleb within the tissue of the eye,* of claim 43, is pure fiction and consequently an erroneous application of a reference to create a section 102 rejection. The manifest error continues when the examiner reads a catheter that is inserted into the blood vessel by the insertion cannula of Kousai as being an anchoring means, equivalent to the recited *anchoring means* of dependent claim 44.

Transferring the ligature 95 of the Ordich injectable glaucoma implant plate to the catheter insertion cannula of Kousai to defeat Appellant's dependent claim 47 is a stretch of the motivation requirement of a proper section 103 rejection that is impossible to reconcile or justify on any ground.

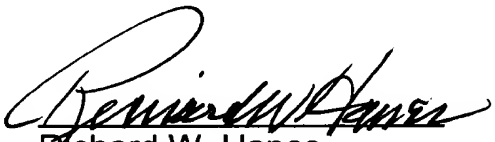
For the specified reasons, the examiner's rejections of claims 43, 44 and 47 are outside of the parameters permitted by law and should be reversed. Such action by the Board is respectfully requested.

Following the Board's reversal of the rejection of claim 43, the Board is also requested to hold that claim 43 is generic to the elected species and to the species of the invention defined by withdrawn dependent claims 45 and 48-50. Accordingly the Board is respectfully urged to declare those claims allowable.

Overruling of the examiner's rejection of claims 43, 44 and 47, and the allowance of claims 45, and 48-50 is respectfully requested.

Dated: June 8, 2004

Respectfully Submitted



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Vickie L. Hensley June 8, 2004